DEC 2 6 2013

# 510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: **K132095**

## I. Applicant Information


Applicant:

Olea Medical
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Application Correspondent:

Same as Applicant


Date Prepared: October 8, 2013

## II. Device Name and Classification

| | |
|---|---|
| Proprietary Name: | Olea Sphere v2.3 |
| Common/Usual Name: | PACS |
| Classification Name: | Picture Archiving Communications System |
| Regulation Number: | 21 CFR 892.2050 |
| Product Codes: | LLZ |
| Classification: | Class II |
| Classification Panel: | Radiology Devices |

## III. Predicate Devices

The Olea Sphere v2.3 device is substantially equivalent to its cleared predicate model. Both models have the same fundamental scientific technology and intended use:

| | |
|---|---|
| 510(k) Number: | K120196 |
| Proprietary Name: | Olea Sphere |
| Common/Usual Name: | PACS |
| Classification Name: | Picture Archiving Communications System |
| Regulation Number: | 21 CFR 892.2050 |
| Product Codes: | LLZ |
| Classification: | Class II |
| Classification Panel: | Radiology Devices |

## IV. Device Description

Olea Sphere is a medical viewing, analysis and processing software package (PACS) compliant with the DICOM standard and running on Windows, Macintosh or Linux operating systems.

Olea Sphere allows the display, analysis and post-processing of medical images.

These images, when interpreted by a trained physician, may yield clinically useful information.

## V. Indications for Use

Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as:

Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.

## VI. Substantial Equivalence Discussion

The following table compares the features of the Olea Sphere v2.3 to its predicate Olea Sphere, since the two devices have the same fundamental scientific technology and intended use.

## Comparison Table

| Device Name | Olea Sphere - K120196 | Olea Sphere v2.3 - K132095 | Changes |
|---|---|---|---|
| **Product Code** | LLZ | LLZ | None |
| **Regulation #** | 892.2050 | 892.2050 | None |
| **Class** | II | II | None |
| **Intended Use** | Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.<br><br>Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).<br><br>The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white | Olea Sphere v2.3 is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.<br><br>Olea Sphere v2.3 provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).<br><br>The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white | None |

| Device Name | Olea Sphere - K120196 | Olea Sphere v2.3 - K132095 | Changes |
|---|---|---|---|
| | matter structure in the brain or more generally the central nervous system.<br><br>The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as:<br><br>Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.<br><br>Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space. | matter structure in the brain or more generally the central nervous system.<br><br>The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as:<br><br>Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.<br><br>Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space. | |
| **Environment of Use** | Olea Sphere is for use in hospitals, imaging centers, radiologist reading practices by professional who requires and is granted access to patient image, demographic and report information. | Olea Sphere v2.3 is for use in hospitals, imaging centers, radiologist reading practices by professional who requires and is granted access to patient image, demographic and report information. | None |
| **Limitations of Use** | Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. | Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. | None |

| Device Name | Olea Sphere - K120196 | Olea Sphere v2.3 - K132095 | Changes |
|---|---|---|---|
| **Principles of Operation** | The Olea Sphere software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters.<br><br>Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including diffusion weighted MRI (DWI) / fiber tracking, and dynamic analysis (dynamic contrast enhanced imaging data for MRI and CT).<br><br>DWI / Fiber Tracking Module: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.<br><br>Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging, showing properties of changes in contrast over time where such techniques are useful or necessary. This | The Olea Sphere v2.3 software offers comprehensive functionality for dynamic image analysis and visualization, where signal changes over time are analyzed to determine various modality dependent functional parameters.<br><br>Olea Sphere v2.3 provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including diffusion weighted MRI (DWI) / fiber tracking, and dynamic analysis (dynamic contrast enhanced imaging data for MRI and CT).<br><br>DWI / Fiber Tracking Module: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.<br><br>Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging, showing properties of changes in contrast over time where such techniques are useful or necessary. This | None |

| Device Name | Olea Sphere - K120196 | Olea Sphere v2.3 - K132095 | Changes |
|---|---|---|---|
| | functionality includes dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow (perfusion) and tissue blood volume as well as leakage (due to capillary permeability) of the injected contrast material from the intravascular to the extracellular space. This functionality is referred to as:<br><br>Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume.<br><br>Permeability Module: Calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space. | functionality includes dedicated analysis methods and visualization tools for dynamic contrast enhanced imaging data (from MRI or CT) where a bolus injection of a contrast agent material results in a temporal change in the signal intensity. This dynamic change in signal intensity is used to calculate functional parameters related to tissue flow (perfusion) and tissue blood volume as well as leakage (due to capillary permeability) of the injected contrast material from the intravascular to the extracellular space. This functionality is referred to as:<br><br>Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume.<br><br>Permeability Module: Calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space. | |

| Device Name | Olea Sphere - K120196 | Olea Sphere v2.3 - K132095 | Changes |
|---|---|---|---|
| **Performance Characteristics:**<br><br>**Image Analysis** | Qualitative or quantitative analysis of certain features in an image or an image set:<br>• Volume of interest (VOI) analysis;<br><br>Segmentation of volumes of interest based on:<br>- A region growing method<br>- Manual delineation | Qualitative or quantitative analysis of certain features in an image or an image set:<br>• Volume of interest (VOI) analysis;<br><br>Segmentation of volumes of interest based on:<br>- A region growing method<br>- Manual delineation<br>- Region-based volume segmentation<br><br>• Histogram normalization<br>• Image subtraction | Enhanced Volume of Interest segmentation with a more automatic volume segmentation method equivalent to the region growing.<br><br>The segmentation is always supervised by the user that can always adjust the segmentation with the existing manual delineation tools.<br><br>Enhanced visualization and comparison of images with histogram normalization and image subtraction. |
| **Performance Characteristics:**<br><br>**Perfusion** | • State of the art deconvolution algorithm:<br>o sSVD (standard);<br>o cSVD (block circulant);<br>o oSVD (adaptative).<br><br>**(Deconvolution)**<br>The deconvolution process is implemented by the Singular Value Decomposition (SVD). Perfusion maps and the singular value decomposition are defined in **References [1, 2]**. | • State of the art deconvolution algorithm:<br>o sSVD (standard);<br>o cSVD (block circulant);<br>o oSVD (adaptative);<br>o probabilistic, bayesian method.<br><br>**(Deconvolution)**<br>The deconvolution process is implemented either by the Singular Value Decomposition (SVD) or probabilistically by a Bayesian algorithm.<br>Perfusion maps and the singular value decomposition and the probabilistic Bayesian method are defined in **References [1, 2, 3]**. | The fundamental scientific technology is the same (being based on the same perfusion model and deconvolution process). The Bayesian probability is a standard methodology that is known to outperform the SVD in terms of accuracy. |

| Device Name | Olea Sphere - K120196 | Olea Sphere v2.3 - K132095 | Changes |
|---|---|---|---|
| **Performance Characteristics:**<br><br>**Permeability** | • State of the art kinetic modeling with vascular deconvolution algorithm.<br>• Generation of permeability maps using signal conversion based on relative signal enhancement:<br>o Area under the curve (AUC);<br>o Peak enhancement (PEAK);<br>o initial up-slope of the curve (Washin);<br>o Down-slope of the curve (Washout);<br>o Time To Peak enhancement(TTP);<br>o Rate constant for transfer of contrast agent from plasma to extravascular, extracellular space (EES) (Ktrans)<br>o Rate constant for transfer of contrast agent from EES to plasma (Kep)<br>o Fractional volume of EES (Ve)<br>o Plasma volume (Vp) | • State of the art kinetic modeling with vascular deconvolution algorithm.<br>• Generation of permeability maps using signal conversion based on relative signal enhancement or T1 mapping:<br>o Area under the curve (AUC);<br>o Peak enhancement (PEAK);<br>o initial up-slope of the curve (Washin);<br>o Down-slope of the curve (Washout);<br>o Time To Peak enhancement (TTP);<br>o Peak percentage enhancement (PEAK_ENHANCEMENT);<br>o Relative washout (CURVE_WASHOUT);<br>o Signal Enhancement Ratio (SER);<br>o Rate constant for transfer of contrast agent from plasma to extravascular, extracellular space (EES) (Ktrans)<br>o Rate constant for transfer of contrast agent from EES to plasma (Kep)<br>o Fractional volume of EES (Ve)<br>o Plasma volume (Vp)<br>o Pre-contrast T1 (T10) | The fundamental scientific technology is the same (being based on the same kinetic modeling and compartmental models).<br><br>The T1-mapping allows loading additional image series (MRI sequences) that are more and more commonly acquired in clinical settings. These additional image series make it possible to convert the transient signal response into concentration values following rapid administration of a contrast agent.<br><br>The kinetic curve type assessment allows permeability parameter estimation in case of acquisitions with a lower temporal resolution. |

| Device Name | Olea Sphere - K120196 | Olea Sphere v2.3 - K132095 | Changes |
|---|---|---|---|
| | **Permeability Output Maps:**<br><br>AUC, TTP, Washin, Washout, Peak, Ktrans, Kep, Ve, Vp. | **Permeability Output Maps:**<br><br>AUC, TTP, Washin, Washout, Peak, PEAK_ENHANCEMENT, CURVE_WASHOUT, SER, Ktrans, Kep, Ve, Vp. T10.<br><br>**Permeability Algorithms:**<br><br>**(T1 mapping)**<br>Estimation of pre-contrast T1 map from additional MR sequences | |
| **Performance Characteristics:**<br><br>**Diffusion Weighted Imaging / Tensor Imaging** | **Diffusion Algorithms:** | **Diffusion Algorithms:**<br><br>**(Motion Correction)** | Availability of the existing motion correction algorithm (perfusion and permeability modules) in the DWI and DTI module. |
| **Performance Characteristics:**<br><br>**Software configuration and module execution** | • Software configuration:<br><br>o Factory pre-defined settings (editable through properties files) | • Software configuration:<br><br>o Factory pre-defined settings (editable through user interface)<br>o User-defined settings<br>o Workflow-driven use | Enhanced configuration of the software.<br>A workflow is made of a list of modules that are executed successively in a sort of wizard mode with user-defined settings. |

References


| # | Document Identifier | Document Title |
|---|---|---|
| [1] | Magnetic Resonance in Medicine 36:715-725 (1996) | High resolution measurement of cerebral blood flow using intravascular tracer bolus passages. Part I: Mathematical approach and statistical analysis. Leif Østergaard, Robert M. Weisskoff, David A. Chesler, Carsten Gyldensted, Bruce R. Rosen |
| [2] | Magnetic Resonance in Medicine 50:164-174 (2003) | Tracer arrival timing-insensitive technique for estimating flow in MR perfusion-weighted imaging using singular value decomposition with a block-circulant deconvolution matrix. Wu O, Østergaard L, Weisskoff RM, Benner T, Rosen BR, Sorensen AG. |
| [3] | IEEE Trans Med Imaging 2012 Jul; 31(7):1381-95 | Bayesian hemodynamic parameter estimation by bolus tracking perfusion weighted imaging. T. Boutelier, K. Kudo, F. Pautot, and M. Sasaki |

## VII. Non-Clinical Performance Data

Olea Medical has conducted extensive verification and validation testing of the Olea Sphere v2.3, as a PACS that is capable of providing reliable post-processing and display of images for instantaneous multi-parametric analysis. All of the different components of the Olea Sphere software have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate safely and effectively.

The Olea Sphere v2.3 complies with the applicable voluntary standards related to PACS systems. The device passed all the testing in accordance with national and international standards.

## VIII. Clinical Performance Data

No clinical testing was conducted in support of the Olea Sphere v2.3, as the indications for use are equivalent to those of its predicate model, the Olea Sphere. These types of devices have been on the market for many years with proven safety and efficacy of use. The non-clinical testing detailed in this submission supports the substantial equivalence of this device.

## IX. Statement of Substantial Equivalence

Based on identical intended use and technological characteristics, the Olea Sphere v2.3 is substantially equivalent to its predicate model, the Olea Sphere.

The Olea Sphere v2.3, as designed and manufactured, does not raise new questions regarding its safety and effectiveness as compared to the predicate model and is determined to be substantially equivalent to the predicate model, the Olea Sphere.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olea Medical
% Ms. Caroline Lene
Quality Manager
93 avenue des Sorbiers, Zone Athelia IV
La Ciotat 13600
FRANCE

May 8, 2014

Re: K132095
Trade/Device Name: Olea Sphere v2.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 8, 2013
Received: October 15, 2013

Dear Ms. Lene:

This letter corrects our substantially equivalent letter of December 26, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K132095

Device Name
Olea Sphere v2.3

Indications for Use *(Describe)*
Olea Sphere is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

Olea Sphere provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI) / Fiber Tracking Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT).

The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system.

The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary. This functionality is referred to as:

Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume.

Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

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